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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,108	07/21/2000	SUSAN ANN CHARMAN	13627	9165
7590 03/10/2004				
SCULLY SCOTT MURPHY & PRESSER 400 GARDEN CITY PLAZA GARDEN CITY, NY 11530			EXAMINER CANELLA, KAREN A	
			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,108

Applicant(s)

CHARMAN ET AL.

Examiner

Karen A Canella

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1, 6-15, 20-26, 28-30, 32 and 34-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1, 6-15, 20-26, 28-30, 32, 34-60 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

1. Claims 2, 3 and 16-18 have been canceled. Claim 45 has been amended. Claims 56-60 have been added. Claims 1, 6-15, 20-26, 28-30, 32, 34-60 are under consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
3. The rejection of claims 1, 6-15, 20-26, 28-30, 32, 34-55 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons of record. Newly added claims 57-60 are also rejected for the same reasons of record.

The instant claims are drawn to compositions comprising leukemia inhibitory factor, or a derivative or homolog thereof. The specification defines leukemia inhibitory factor as synthetic, recombinant or purified naturally occurring LIF from animal or avian species. Thus, the specification does not provide any particular definition for leukemia inhibitory factor. In this circumstance, leukemia inhibitory factor will take its definition from the ordinary usage in the art. The art recognizes LIF as a synonym for at least nine different factors defined on the basis of their effect on a variety of cell types including lymphomas, liver cells, embryonic stem cells and carcinoma cells (see abstract of Van Vlasselaer et al, Prog Growth Factor Res, 1992, Vol. 4, pp. 337-353). More recently, it has been recognized that LIFs are structurally related to cytokines such as Il-6, oncostatin M, ciliary neurotrophic factor, Il-11 and cardotrophin-1, and in addition have redundant activities with said cytokines (see abstract of Taupin et al, Int Rev Immunol, 1998, Vol. 16, pp. 397-426). Thus, LIFs are part of a family of cytokines, and the claimed derivatives homologs or functional equivalents thereof read on Il-6, oncostatin M, ciliary neurotrophic factor, Il-11 and cardotrophin-1, as well as LIFs from other species, allelic variants, mutants and LIFs as yet to be discovered. It is noted that the term LIF is defined by the specification as including all derivative and homologs of LIFs as well as synthetic recombinant or purified naturally occurring LIF from animal or avian species. Thus, the claims are drawn to a genus of proteins. Furthermore, said genus is highly variant because neither the specification nor

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the claims place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to LIF within the scope of homologs or functional equivalents thereof. Further, the ordinary usages of the term "derivative" encompasses any possible chemical modification as well as multiple chemical modifications. It can be concluded that the specification fails to teach the common structural attributes of members of the claimed genus. The specification states on page 4 that LIF includes derivatives, homologs, mimetics and analogues include parts, fragments or portions of LIF which are functionally active or which otherwise have a useful biological activity (eg. as an antagonist, antigen to induce antibody formation, as a diagnostic or therapeutic molecule). In light of the fact that any fragment of any protein has a useful biological activity in that it can be used to raise an antibody, the definition in the specification fails to place a limitation on the specific functional characteristic of the claimed genus, and the art teaches that the LIF proteins have pleiotropic effects, and are active on a wide variety of cell or tissue types (Van Vlasselaer et al, *ibid*, and the abstract of Hilton et al, *Journal of Cell Biochemistry*, 1991, Vol. 46, pp. 21-26). Thus, the limitation of "functional equivalents" or "homologue" does not signify a specific functional characteristic that one of skill in the art could use to determine if a given protein was excluded or included within the claimed genus. Since the disclosure fails to identify common structural and functional attributes of the members of the claimed genus, and because the genus is highly variant, the recitation of LIF is insufficient to describe the genus. One of skill in the art would conclude that the disclosure fails to provide a representative number of species to describe the claimed genus. Therefore applicant was not in possession of the claimed genus at the time of filing.

Applicant argues that the term LIF is commonly used by one skilled in the art to uniquely identify proteins from various animal species, which are characterized by certain structural and functional features and therefore its meaning is unambiguous and clearly understood by those skilled in the art. This has been considered but not found persuasive, because the specification states that LIF includes all derivative and homologs, as well as synthetic recombinant or purified naturally occurring LIF from animal or avian species. The definition in the specification includes derivatives, homologues and allelic variants. For the reason set forth above, the term LIF cannot adequately describe the derivative, homologues or variants of LIF because the genus is highly variant. Structural and functional attributes which could be used to determine whether

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a given molecule was part of the genus are missing from the specification and the claims. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus.

Applicant argues that one of skill in the art would understand by evidence of the attached exhibits that LIF is a group of proteins uniquely identified by structural and functional features which distinguish it from other cytokines. This has been considered but not found persuasive. due to the teachings in the specification which states on page 4 that LIF includes derivatives, homologs, mimetics and analogues include parts, fragments or portions of LIF which are functionally active or which otherwise have a useful biological activity (eg. as an antagonist, antigen to induce antibody formation , as a diagnostic or therapeutic molecule). Clearly the specification encompasses molecules which have numerous structural deviations from the LIF disclosed in the exhibits filed Sept 15, 2003.

4. All other rejections and objections as stated in the prior Office action are withdrawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828.

The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
Primary Examiner, Art Unit 1642
03/08/04


KAREN A. CANELLA PH.D
PRIMARY EXAMINER